

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0892637	(X3) Date Survey Completed 05/20/2021
Name of Provider or Supplier Pediatric Care Center	Street Address, City, State 304 East 4th Street, Anniston, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a review of the CMS (Centers for Medicare and Medicaid Services) CASPER reports (#153/#155) and API (American Proficiency Institute) proficiency testing evaluations, the surveyor determined the laboratory failed two consecutive testing events for Hemoglobin [(Hgb) Hematology testing], resulting in an initial unsuccessful proficiency testing participation. This affected Event #3, 2020 and Event #1, 2021. The findings include: 1. A review of the CASPER reports on May 20, 2021 revealed the laboratory scored sixty percent (60 %) for Hgb for Event #3, 2020 and Event #1, 2021, two consecutive testing events. 2. The API proficiency testing evaluation confirmed the above noted findings.

D2130**HEMATOLOGY**

CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a review of the CMS (Centers for Medicare and Medicaid Services) CASPER reports (#153/#155) and API (American Proficiency Institute) proficiency testing evaluations, the surveyor determined the laboratory failed to successfully perform in two consecutive testing events for Hemoglobin [(Hgb) Hematology testing], Event #3, 2020 and Event #1, 2021. These failures resulted in an initial unsuccessful proficiency testing participation (Refer to D2016). The findings include: 1. A review of the CASPER reports on May 20, 2021 revealed the laboratory scored sixty percent (60 %) for Hgb for Event #3, 2020 and Event #1, 2021, two consecutive testing events. 2. The API proficiency testing evaluation confirmed the above noted findings.